K013707 p.1/2

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ATTACHMENT 6

510(k) Summary

(As required by 21 C.F.R. § § 807.87(h), 807.92)

Date of Submission November 8, 2001

Identification of Applicant

Applicant

Global TV Concepts, Ltd.
676 South Military Trail
Deerfield Beach, Florida 33442

Contact Person

Laurie Braden
President
(954) 570-9999

Trade or Proprietary Name Softique™ Paraffin Bath
GI-111001

Common Name Paraffin Bath

Classification Name Paraffin Bath

Classification II

Intended Use

The Softique™ Paraffin Bath is an over-the-counter device intended for the following uses:

1. Useful in symptomatic relief of pain caused by arthritis, bursitis, and chronic joint inflammation
2. Relaxes muscles, relieves stiffness and muscle spasm
3. Stimulates circulation and for other conditions where heat is indicated

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Device Description

The Softique™ Paraffin Bath is a full-size paraffin bath with a paraffin wax capacity of five pounds (with a recommended use of three to four pounds of paraffin wax), a melting time for the paraffin wax of approximately five hours, and a temperature range for the paraffin wax of 123-130°F. The unit utilizes two heaters with a total of 90 W in order to melt and maintain the temperature of the melted paraffin wax. The unit has an operation voltage of 120 V, 60 Hz. The Softique™ Paraffin Bath is supplied with a power cord, a plastic lid, three pounds of pure, hypo-allergenic paraffin wax, and 60 plastic liners.

Substantial Equivalence

The Softique™ Paraffin Bath is substantially equivalent to the following models of paraffin baths currently in commercial distribution:

1.	ParaSpa™ (PAR-200) Paraffin Bath by Homedics	K001860
2.	Therabath® by W.R. Medical Electronics Co.	pre-amendment device

Technological Characteristics

Substantial equivalence is claimed because intended uses, directions for use, technology, and operating principles are the same for all three devices. Technical differences do not affect the safety or efficacy of the product. Other differences between the devices are cosmetic in nature.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 1 2002

Ms. Laurie Braden
President
Global TV Concepts, LTD
676 South Military Trail
Deerfield Beach, Florida 33442

Re: K013707
Trade/Device Name: Softique Paraffin Bath
Regulation Number: 21 CFR 890.5110
Regulation Name: Paraffin Bath
Regulatory Class: II
Product Code: IMC
Dated: November 8, 2001
Received: November 8, 2001

Dear Ms. Braden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ATTACHMENT 8

INDICATIONS FOR USE STATEMENT

510(k) Number: K013707

Device Name: Softique™ Paraffin Bath

Indications for Use:

1. Useful in symptomatic relief of pain caused by arthritis, bursitis, and chronic joint inflammation
2. Relaxes muscles, relieves stiffness and muscle spasm
3. Stimulates circulation and for other conditions where heat is indicated

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-the-Counter Use ✓

(Per 21 C.F.R. § 801.109)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013707